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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,469	12/03/2001	Ziv Shani	01/22924	3374

7590 05/06/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,469	SHANI ET AL.	
	Examiner	Art Unit	
	Joseph T. Voitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/7/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application filed December 3, 2001 is a national stage filing of PCT/IL00/00330, filed June 7, 2000, which is a continuation in part of 09/329,234, filed June 10, 1999, now US Patent 6,331,416.

Applicants' amendment filed April 10, 2002, paper number 7, has been received and entered. Claims 1-25 have been cancelled. Claims 26-28 have been added. Claims 26-28 are pending and currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 4, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

However, the listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." More specifically, the specification provides citations that have not been provided in the form of an IDS (see for example pages 4-6 and 18-24). Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 26 is vague and unclear in the recitation of “a unique amino acid sequence” because the what is encompassed by unique is not clearly set forth. It is unclear if the sequence must have never been identified to be unique, or at what point any sequence would be considered unique. It is unclear if the sequence must be unique to one or the two other portions of the fusion protein or unique in itself. In addition, it is unclear what the metes and bounds of “a controllable intervening protein sequence” is and what is being controlled or how it is related to the other portions of the fusion protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(f) he did not himself invent the subject matter sought to be patented.

Claims 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoseyov *et al.* (US Patent 5,670,623).

Shoseyov *et al.* teach a CBD fusion protein that has a cleavable sequence between the CBD and the second portion of the fusion protein (see for example claim 6). The cleavable site

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can be affected both chemically and enzymatically (claims 7 and 8). Shoseyov *et al.* provide guidance for host cells including guidance for viral vectors and promoters to generate the fusion protein in a plant system.

Claims 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shoseyov *et al.* (US Patent 5,719,044).

Shoseyov *et al.* teach a CBD fusion protein that has a cleavable sequence between the CBD and the second portion of the fusion protein (see for example claims 29 and 31). The cleavable site can be affected both chemically and enzymatically (claims 32 and 33). Shoseyov *et al.* provide guidance for host cells including guidance for viral vectors and promoters to generate the fusion protein in a plant system.

Claims 26-28 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. In the instant case, the specification of both '623 and '044 contain teachings that anticipate the instantly claimed invention, however the inventive entity between the present application and that of '623 and '044 is different. The common inventor Shoseyov is noted, however there are several additional inventors that are listed in the issued patents while Shani is present on the instant application but not the issued patents. Importantly, the issued patents encompass methods that make obvious the instantly claimed product. It is noted that none of the issued claims specifically set forth that the host cell is a plant system, however the teachings in the specification of '623 and '044 provide clear guidance for this being one of the host cells contemplated. It is unclear given the similarity in guidance between the issued patents

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and the instant specification why the inventive entity differs, in particular since the instantly claimed product would be an obvious choice as a host cell in use of the patented methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,670,623 and over claims 27-34 of U.S. Patent No. 5,719,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because each patent is drawn to a method of protein production and isolation of a recombinantly generated CBD fusion protein. Though none of the claims specifically set forth that the host cell used to produce the CBD fusion protein is a plant cell, the specification provides detailed guidance for viral vectors and promoters for expression of the protein in plant systems making it one of the obvious choices for a host cell (see '623 column 15 and '044 column 14, for example).

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shani *et al.* (US Patent 6,331,416) is the priority document relied upon by the instant application.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

A handwritten signature in cursive script that reads "Joe Woitach". The signature is written in black ink and is positioned below the typed name "Joseph T. Woitach".